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Re-evaluation Decision

RVD2014-08

p-Chloro-m-cresol and Sodium p-Chloro-m-cresolate

(publié aussi en français)

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Re-evaluation Decision

p-Chloro-m-cresol and sodium p-chloro-m-cresolate are broad-spectrum antimicrobial active ingredients used as material preservatives. There are two products containing p-chloro-m-cresol that are currently registered in Canada under the authority of the *Pest Control Products Act*, including one technical grade active ingredient and one commercial class end-use product. There are three products containing sodium p-chloro-m-cresolate that are currently registered, including one technical grade active ingredient and two commercial class end-use products.

After a re-evaluation of p-chloro-m-cresol and sodium p-chloro-m-cresolate, Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act*, is granting continued registration of products containing p-chloro-m-cresol and sodium p-chloro-m-cresolate for sale and use in Canada. An evaluation of available scientific information found that products containing p-chloro-m-cresol and sodium p-chloro-m-cresolate do not present unacceptable risks to human health or the environment when used according to the conditions of registration, which include amended label directions. p-Chloro-m-cresol and sodium p-chloro-m-cresolate were found to have value when used as material preservatives in industrial settings. As a condition of the continued registration of p-chloro-m-cresol and sodium p-chloro-m-cresolate, label amendments are required for all end-use products. Appendix I lists the required label amendments. No additional data are requested at this time.

The PMRA's pesticide re-evaluation program considers potential risks, as well as value, of pesticide products to ensure they meet modern standards established to protect human health and the environment. Regulatory Directive DIR2012-02, *Re-evaluation Program Cyclical Re-evaluation*, presents the details of the cyclical re-evaluation approach, which is in line with the requirements of the *Pest Control Products Act*. Re-evaluation draws on data from registrants, published scientific reports, information from other regulatory agencies and any other relevant information available.

This re-evaluation decision,¹ previously proposed in the consultation document, Proposed Re-evaluation Decision PRVD2013-03, *p-Chloro-m-cresol and Sodium p-Chloro-m-cresolate*, describes the decision-making stage of the PMRA's regulatory process and summarizes the Agency's decision and the reasons for it. No comments were received during the consultation process. Therefore, this decision is consistent with the proposed re-evaluation decision stated in PRVD2013-03. Please refer to both the Overview and more detailed Science Evaluation sections of PRVD2013-03 for the human health, environmental and value considerations underlying this re-evaluation decision. A reference list for all data used as the basis for the re-evaluation decision is also included in PRVD2013-03.

To comply with this decision, the registrant of p-chloro-m-cresol and sodium p-chloro-m-cresolate products will be informed of the specific requirements affecting their product registration(s) and of the regulatory options available to them.

¹ "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

Other Information

Any person may file a notice of objection² regarding this decision on p-chloro-m-cresol and sodium p-chloro-m-cresolate within 60 days from the date of publication of this Re-evaluation Decision document. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the Pesticides and Pest Management portion of Health Canada's website (Request a Reconsideration of Decision) or contact the PMRA's Pest Management Information Service.

² As per subsection 35(1) of the *Pest Control Products Act*.

Appendix I Label Amendments for Products Containing p-Chloro-m-cresol and Sodium p-Chloro-m-cresolate

The label amendments presented below do not include all label requirements for individual end use products, such as first aid statements, disposal statements, precautionary statements and supplementary protective equipment. Information on labels of currently registered products should not be removed unless it contradicts the following label statements.

The labels of end-use products must be amended to include the following statements to further protect workers and the environment.

I. The following statements must be included in the section entitled **PRECAUTIONS**:

Wear protective eyewear (goggles or face shield), chemical-resistant coveralls over long-sleeved shirt and long pants, and chemical-resistant gloves and footwear during handling, clean up, and repair activities, and when handling treated metalworking fluid concentrates.

II. The following statements must be included in the section entitled **DIRECTIONS FOR USE**:

DO NOT contaminate irrigation or drinking water supplies or aquatic habitats by cleaning of equipment or disposal of wastes.

DO NOT discharge effluents containing this product into sewer systems, lakes, streams, ponds, estuaries, oceans, and other waters.